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CANDELA

K021190

General Information:

This 510(k) is to provide notification of substantial equivalence for the Candela Vbeam Pulsed Dye Laser System, which is substantially equivalent to previously marketed devices intended for photocoagulation of benign cutaneous vascular lesions, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, Poikiloderma of Civatee and benign cutaneous lesions, such as warts, scars, striea and psoriasis. Photocoagulation of benign cutaneous lesion and benign vascular lesion in Gynecology. Treatment of periorbital wrinkles and wrinkles.

Submitted by:	Candela Corporation 530 Boston Post Road Wayland, MA 01778-1886
Contact Person:	Lorraine Nelson
Date Prepared:	April 11, 2002
Classification:	Class II (21 CFR § 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)
Common Name:	Dermatology Laser, Vbeam Pulsed Dye Laser System
Predicate Devices:	Candela Vbeam Pulsed Dye Laser (K013784), SLS Biophile Ltd NLite (K013461)

Description:

The Vbeam is a 595 nm flash-lamp excited pulsed dye medical laser, controlled by an embedded microprocessor, to be used for the treatment of benign cutaneous vascular lesions, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, Poikiloderma of Civatee and benign cutaneous lesions, such as warts, scars, striea and psoriasis. Photocoagulation of benign cutaneous lesion and benign vascular lesion in Gynecology. Treatment of periorbital wrinkles and wrinkles. The Vbeam laser is used with the Candela Dynamic Cooling Device, which provides a short burst of cryogen spray prior to firing the laser pulse. The laser output energy is delivered via an optical fiber to a handpiece, which produces circular beams with diameters of 5, 7, 10 and 3 x 10 millimeters on the skin. The cryogen, which is housed within the laser enclosure, is delivered via a hose to a nozzle located in the handpiece.

The Candela Vbeam Pulsed Dye Laser is equipped with safety interlock systems to protect patients and operators. Users of the device make selections from an onboard control panel to regulate operation during treatment.

Testing:

As a laser product, the Vbeam Pulsed Dye Laser is required to conform and does conform to the Laser Performance Standard (21 CFR 1040). In addition the Vbeam conforms to the UL 2601 Electrical Safety Standard and with the Harmonized Standard EN 60601-1-2, Part 2 established by and required by the European Community.

Summary of Substantial Equivalence:

The Candela Vbeam Laser has the same intended use, utilizes similar operating principles and matches key design aspects, including similar spot size, the same wavelength and / or the same maximum delivered power as the predicate devices.

On the basis of similarities in methods of assembly, method of operation, clinical performance data and intended uses, Candela Corporation believes that its Candela Vbeam Laser System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2002

Candela Corporation
Lorraine Nelson
Manager, Regulatory Affairs
530 Boston Post Road
Wayland, Massachusetts 01778-1886

Re: K021180
Trade Name: Candela Vbeam Pulsed Dye Laser System
Regulation Number: 878.4810
Regulation Name: Laser Surgical Instrument
Regulatory Class: II
Product Code: GEX
Dated: April 11, 2002
Received: April 15, 2002

Dear Ms. Nelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CANDELA

510(k) Number (if known): K 021180

Device Name: Candela Vbeam Pulsed Dye Laser System

Indications For Use:

The Candela Vbeam Pulsed Dye Laser is indicated for the following uses in:

General Surgery: Photocoagulation of benign cutaneous vascular lesion and benign cutaneous lesions.

Dermatology/Plastic Surgery: For treatment of benign cutaneous vascular lesion, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, Poikiloderma of Civatte, and benign cutaneous lesions, such as warts, scars, striea and psoriasis. Periorbital wrinkles and the treatment of wrinkles.

Gynecology: Photocoagulation of benign cutaneous lesion and benign vascular lesion in gynecology.

Podiatry: Treatment of benign cutaneous lesion, such as warts.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021180

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional format 1-2-96)